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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/047,587 | 01/15/2002 | Nabil L. Muhanna | M112 1100 | 4693 |

7590 08/01/2003

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[REDACTED] EXAMINER

MELSON, CANDICE C

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| | 3732 |

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/047,587 | MUHANNA, NABIL L. |
| Examiner | Art Unit | |
| Candice C. Melson | 3732 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6, 8, 10, 11, 14, 15, 17-20, 23 and 24 is/are rejected.
- 7) Claim(s) 5, 7, 9, 12, 13, 16, 21, 22 and 25 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 15 January 2002 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Drawings

New corrected drawings are required in this application because the drawings are informal. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Information Disclosure Statement

The information disclosure statement filed 04/11/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. In particular, references I-N were not considered by the Examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 6 recites the limitation "the at least one predetermined line" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

1) Claims 1,2,4,15, 17 -18, 20 and 23-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuntz (USPN 4,349,921). Kuntz discloses, with respect to Claims 1-2, "one embodiment of the intervertebral disc prosthesis according to the invention is shown at 10 in FIGS. 1,2, and 3. The prosthesis 10 is formed of a thin block of biologically acceptable material having slightly convex superior and inferior surfaces 11 and 12, transverse grooves 13 in said

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superior and inferior surfaces and also in both lateral surfaces 14, 14, a flange or lip 15 raised from said superior and inferior surfaces at one longitudinal end of the prosthesis, and a wedge shaped tapering portion 16 at the other longitudinal end" (column 6, lines 9-18). This also anticipates Claim 15. Furthermore, Kuntz teaches, "the wedge shaped tapering portion 16 allows for easier insertion of the prosthesis into the disc space" (column 6, lines 67-68). As to Claims 17-18, "the prosthesis 10 is essentially a spacer and can be fabricated from any biologically acceptable material of suitable strength and durability, for example high density polyethylene, polymethylmethacrylate, stainless steel, or chrome cobalt alloys. The simplest material fabrication of the prosthesis is a polymer, preferably high density polyethylene" (column 7, lines 52-58). This also anticipates Claims 2 and 4. With regards to Claims 20 and 23-24, a method of maintaining intervertebral space between adjacent vertebrae is disclosed wherein "the diseased discs are excised anteriorly and the space is thoroughly curetted out, removing the whole of the disc" (column 10, lines 18-20). "Once the space has been well curetted out to the posterior aspects of the body and while traction is being applied to the neck by the anesthetist, the intervertebral disc prosthesis 10 is tapped into position" (column 10, lines 32-35).

2) Claims 1-4, 14, and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Gauchet (USPN 6,395,032). Gauchet's invention "provides an intervertebral disc prosthesis comprising a compressible cushion having a body made of a material, and a liquid which is able to come into contact with the body" (column 1, lines 47-49). "The prosthesis has a cushion 14 interposed between the plates 4. This cushion comprises bellows or folded laminate sheets 16. It has a shape, which is symmetrical in revolution about the axis 9. Its wall profile comprises corrugations which make it possible to vary the length of the bellows 16 in the axial direction"

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(column 2, lines 63-67). This anticipates Claims 1-4. Also, as to Claim 2, the laminate 16 includes at least one fastener comprising an adhesive (column 3, lines 8-9). Inherently the prosthesis has an anterior face and a posterior face, as stated in Claim 14. As to Claims 18 and 19, "In this case, the bellows, like the plates, is made of titanium or titanium alloy so that it has a certain degree of axial strength and forms a compression spring" (column 3, lines 2-5). "The wall of the bellows can be made using one, two or three sheets each measuring 0.1mm in thickness" (column 3, lines 19-20).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3) Claims 8,10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz in view of Boyer, III et al (US 2001/0039458). Kuntz discloses the invention as stated in Claim 8 except for the biocompatible material selected from a dissected animal and the dissected animal tissue selected from porcine and bovine tissue. As to Claim 10 Kuntz does not disclose the biocompatible material fixed by a protein cross-linking agent, in particular glutaraldehyde. Boyer, III et al teach a variety of bone grafting materials "another bone-grafting material is disclosed in US Pat. No. 4,678,470 to Nashef et al., and is formed using a tanning procedure involving glutaraldehyde that renders the material osteoconductive. A bone block is shaped into

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a precise predetermined form and size using conventional machining techniques. A paste-like suspension is also formed using known methods of comminuting bone, such as milling, grinding, and pulverizing, and adding the pulverized or powdered bone to a carrier. The treatment of glutaraldehyde allows the use of bovine, ovine, equine, and porcine bone sources. However, it the final desired form of the bone grafting material is a block of bone or machined shape, the bone stock must be large enough to provide a block of the required size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate the tissue of a bovine as well as the protein cross-linking agent as taught by Boyer, III et al in order to provide a prosthesis that stimulates bone growth manufactured from a wider range of biocompatible tissue.

Allowable Subject Matter

Claims 5,7,9,12-13,16,21,22 and 25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim 6 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Candice C. Melson whose telephone number is (703) 305-8128. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Candice C. Melson, Examiner
July 28, 2003


Candice C. O'Connor
Primary Examiner